1615 #8

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PATENT & TRADEMARK OFFICE

In re Patent Application of:

Ralph W. BLUME et al.

Attorney Docket No.: 031853.0003 #9

Application No.: 09/559,542

Group Art Unit: 1615

Filed: April 28, 2000

Examiner: C. Evans

Title: GUAIFENESEN SUSTAINED RELEASE FORMULATION AND TABLETS

Commissioner for Patents
Washington, D.C. 20231

Transmitted herewith is an amendment in the above-identified application. Fees have been calculated as shown below:

CLAIMS AS AMENDED						
	Claims Remaining After Amendment	Highest Number Previously Paid For	Extra	Rate		Amount
				Large Entity	Small Entity	
Number of Claims in Excess of 20	26	32	0	$ 18.00	$ 9.00	$ 0.00
Independent Claims in Excess of 3	1	3	0	$ 80.00	$ 40.00	$ 0.00
First Presentation of Multiple Dependent Claims				$ 270.00	$ 135.00	$135.00
Extension Fee: a) One Month				$ 110.00	$ 55.00	$ 0.00
b) Two Months				$ 390.00	$ 195.00	
c) Three Months				$ 890.00	$ 445.00	
d) Four Months				$1390.00	$ 695.00	
e) Five Months				$1890.00	$ 945.00	
Other: IDS after First Action						$240.00
TOTAL FEE DUE						$375.00

☐ No additional fee is required.
☐ A check in the amount of $ _____ is attached.
☒ Charge $ **375.00** _____ to Deposit Account No. 50-1640.
☒ Charge any additional fees or credit any overpayment to Deposit Account No. 50-1640.

Small Entity Status Claim:
☐ is attached.
☒ is of record in this application.

Respectfully submitted,

By: _____
Rodger L. Tate
Registration No. 27,399

RLT/sdl

A

PATENT
ATTORNEY DOCKET: 031853.0003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application Of:)
)
Ralph W. BLUME et al.) Group Art Unit: 1615
)
Application Number: 09/559,542) Examiner: C. Evans
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Filed: April 28, 2000)
)
For: GUAIFENESIN SUSTAINED RELEASE FORMULATION AND TABLETS

RESPONSIVE AMENDMENT UNDER 37 C.F.R. § 1.111

Commissioner for Patents
Washington, D.C. 20231

Sir:

Responsive to the Office Action mailed May 4, 2001, please amend the above-captioned application as set forth below.

IN THE CLAIMS

Please cancel claims 1-32 and add the following new claims 33-55 provided in a clean format in accordance with 37 C.F.R. § 1.121 as follows:

33. A modified release tablet having two portions, wherein a first portion comprises a first quantity of guaifenesin in an immediate release form which becomes fully bioavailable in the subject's stomach and a second portion comprises a second quantity of guaifenesin and a release-delaying matrix comprising a hydrophilic polymer and a water-insoluble polymer wherein the weight ratio of said hydrophilic polymer to said water-insoluble polymer is in the range of from about 1:1 to about 6.8:1, wherein said tablet demonstrates a C_{max} equivalent to an immediate release guaifenesin product and wherein said tablet also provides therapeutically effective bioavailability for at least twelve hours after dosing in a human subject according to serum analysis.

34. The modified release tablet of claim 33 wherein said hydrophilic polymer is selected from the group consisting of acacia, gum tragacanth, locust bean gum, guar gum, karaya gum, modified cellulosic, methylcellulose, hydroxymethylcellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, hydroxyethylcellulose, carboxymethylcellulose, agar,